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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/020,393	02/09/98	SIMS	BMRF 170

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PATREA L PABST
ARNALL GOLDEN & GREGORY
2800 W PEACHTREE STREET
ATLANTA GA 30309-3450

EXAMINER	
CELSA, B	
ART UNIT	**PAPER NUMBER**
1654	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file copy

Office Action Summary

Application No.	Applicant(s)
09/020,393	Sims, Peter J.
Examiner	**Group Art Unit**
Bennett Celsa	1654

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-35* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-35* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ NOTICE TO COMPLY SEQ RULES

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-35 are currently pending.

It is noted that claims 7, 16, 26 and 33, are improperly dependent and fail to further limit the independent compound claims to which they are dependent. For purposes of restriction, these claims will be viewed to be composition claims.

Please see attached NOTICE TO COMPLY WITH THE SEQUENCE RULES which sets its own period for response..

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-3 and 7, drawn to an antibody protein to CD59 (42-58), classified in class 530, subclass 387.1+ .

   II. Claims 10-12 , 16 and 17 drawn to the use of an antibody protein to CD59 (42-58) and composition thereof for inhibition formation of human C5b-9 complex, classified in class 424, subclass 130.1+ .

   III. Claims 20-22 and 26, drawn to an antibody protein to C9 (359-384), classified in class 530, subclass 387.1.

   IV. Claims 27-29 and 33, drawn to use of an antibody protein to C9 (359-384) to promote formation of human C5b-9 complex , classified in class 424, subclass 130.1+ .

V. Claims 1-3, 7, 20-22 and 26, drawn to an anti-idiotype antibody to both CD59(42-58) and C9(359-384)and composition thereof, classified in class 530, subclass 387.1+..

VI. Claims 10-12, 16, 17, 27-29 and 33-35, drawn to the use of an anti-idiotype antibody to both CD59(42-58) and C9(359-384) and composition thereof for inhibiting and/or promoting formation of human C5b-9 complex classified in class 424, subclass 130.1+ .

VII. Claims 1-2, 4 and 26, drawn to a chimeric protein comprising CD59(42-58)and composition thereof, classified in class 530, subclass 350+.

VIII. Claims 10-11, 13, 16 and 17, drawn to the use of a chimeric protein comprising CD59(42-58) and composition thereof to inhibit human C5b-9 complex classified in class 424, subclass 85.1+.

IX.. Claims 20-21 and 26 , drawn to a chimeric protein comprising human C9 (359-384), classified in class 530, subclass 350+.

X. Claims 27, 28, 30 and 33-35 , drawn to the use of a chimeric protein comprising human C9 (359-384) to promote formation of human C5b-9 complex, classified in class 424, subclass 85.1+.

XI. Claims 1, 2, 6, 7 and 26, drawn to a linear peptide comprising human CD59(42-58) and composition thereof, classified in class 530, subclass 300+.

XII. Claims 10, 11 and 15-17 , drawn to the use of a linear peptide comprising human CD59(42-58) and composition thereof to inhibit human C5b-9 complex, classified in class 514, subclass 2+..

XIII.. Claims 20, 21, 25 and 26, drawn to a linear peptide comprising human C9(359-384) and composition thereof, classified in class 530, subclass 300+

XIV. Claims, 27, 28 and 32-35, drawn to the use of a linear peptide comprising human C9(359-384) and composition thereof to promote formation of human C5b-9 complex, classified in class 514, subclass 2+.

XV.. Claims 1, 2, 5, 6, 7 and 26, drawn to a cyclic peptide comprising human CD59(42-58) and composition thereof, classified in class 530, subclass 317.

XVI. Claims 10, 11 and 14-17 , drawn to the use of a cyclic peptide comprising human CD59(42-58) and composition thereof to inhibit human C5b-9 complex, classified in class 514, subclass 9.

XVII. Claims 20, 21 and 24-26, drawn to a cyclic peptide comprising human C9(359-384) and composition thereof classified in class 530, subclass 317.

XVIII. Claims 27, 28 and 31-35, drawn to the use of a cyclic peptide comprising human C9(359-384) and composition thereof to promote formation of human C5b-9 complex classified in class class 514, subclass 9.

XIX. Claims 7-9, drawn to a peptidomimetic compound comprising the sidechains of human CD59 (His,Asn,Asp,Thr,Thr,Arg,Glu 44,48,49,51,52, 55 and 58,

respectively) and composition thereof, classified in class 530, subclass 323 and class 930, subclasses 21 and 30.

XX. Claims 10, 11 and 16-19, drawn to the use of a peptidomimetic compound comprising the sidechains of human CD59 (His,Asn,Asp,Thr,Thr,Arg,Glu 44,48,49,51,52, 55 and 58, respectively) and composition thereof to inhibit the formation of human C5b-9 complex, classified in class 514, subclass 2+..

XXI. Claims 1, 2 and 7, drawn to a DNA nucleic acid and composition thereof, classified in class 536, subclass 23.1+.

XXII. Claims 10, 11, 16 and 17, drawn to use of a DNA nucleic acid and composition thereof to inhibit C5b-9 complex , classified in class 514, subclass 23+.

XXIII.. Claims 1, 2 and 7, drawn to an RNA nucleic and composition thereof, classified in class 536, subclass 23.1+.

XXIV. Claims 10, 11, 16 and 17 , drawn to the use of an RNA nucleic acid and composition thereof to inhibit formation of human C5b-9, classified in class 514, subclass 23+.

XXV. Claims 20, 21 and 26, drawn to a DNA nucleic and composition thereof, classified in class 536, subclass 23.1+.

XXVI. Claims 27, 28 and 33-35, drawn to a DNA nucleic acid and composition thereof to promote formation of the human C5b-9 complex, classified in class 514, subclass 23+.

XXVII. Claims 20, 21 and 26, , drawn to an RNA nucleic acid and composition thereof, classified in class 536, subclass 23.1+.

XXVIII. Claims 27, 28 and 33-35 drawn to the use of an RNA nucleic acid and composition thereof to promote formation of human C5b-9 complex, classified in class 514, subclass 23+.

XXIX. Claims 1, 2 and 7, drawn to "small molecules" which bind "specifically" to human C9 (359-384) and compositions thereof , which are only classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule" (e.g.due to the relative nature of the term "small" and the lack of any indication as to what structure is encompassed by the term "small molecule").

XXX. Claims 10, 11, 16 and 17, drawn to the use of "small molecules" which bind "specifically" to human C9 (359-384) and compositions thereof to inhibit human C5b-9 complex, classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule" (e.g.due to the relative nature of the term "small" and the lack of any indication as to what structure is encompassed by the term "small molecule").

XXXI. Claims 20, 21 and 26 , drawn to "small molecules" which bind "specifically" to human CD59 (42-58) and compositions thereof, which are only classifiable upon selection of an ultimate compound species due to the indefiniteness of the term

"small molecule" (e.g.due to the relative nature of the term "small" and the lack of any indication as to what structure is encompassed by the term "small molecule").

XXXII. Claims 27, 28 and 33-35, drawn to the use of "small molecules" which bind "specifically" to human CD59 (42-58) and compositions thereof to promote the formation of human C5b-9 complex, which is only classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule" (e.g.due to the relative nature of the term "small" and the lack of any indication as to what structure is encompassed by the term "small molecule").

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions (I and II) and (III and IV) and (V and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case .the process for using the product as claimed can be practiced with another materially different product e.g. using a nucleotide, cyclic/linear peptide or fusion protein and additionally, the product as claimed can be used in a materially different process of using that product such as for affinity purification of the protein.

4. Inventions (VII and VIII) and (XI and XII) and (XVand XVI) and (XIX and XX) and (XXI and XXII) and (XXIII and XXIV) and (XXIX and XXX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case .the process for using the product as claimed can be practiced with another materially different product such as an antibody or any one of VII, XI, XV, XIX, XXI, XXIII and/or XXIX and the product as claimed can be used in a materially different process of using that product such as for use in generating antibodies for affinity purification of the protein or diagnostic use.

5. Inventions (IX and X) and (XIII and XIV) and (XVII and XVIII) and (XXV and XXVI) and (XXVII and XXVIII) and (XXXI and XXXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case .the process for using the product as claimed can be practiced with another materially different product e.g. as an antibody or use of any one of IX, XIII, XVII, XXV, XXVII and/or XXXI and the product as claimed can be used in a materially different process of using that product such as for use in generating antibodies for affinity purification of the protein or diagnostic use.

6. It is noted that in accordance with U.S. practice, upon the allowance of a compound claim within an elected compound invention, the Examiner will *consider rejoinder of* a method of

use of such compound claims which are commensurate in scope to the allowed subject matter

pursuant to MPEP 821.04 Rejoinder

7. The Group I, III and V inventions are drawn to independent and/or patentably distinct antibodies since each would be expected to possess distinctly different structure (e.g. amino acid content, secondary and tertiary structure) and/or functions (e.g. specificity of substrate and degree of binding) and/or be capable of separate manufacture and/or use.

8. The Group VII and IX inventioons are drawn to independent and/or patentably distinct chimeric proteins since each would be expected to (and do) possess distinctly different structure (e.g. amino acid content, secondary and tertiary structure) and/or physicochemical properties) and/or be capable of separate manufacture and/or use.

9. The Group XI and XIII inventions are drawn to independent and/or patentably distinct linear peptides since each would be expected (and do) to possess distinctly different structure (e.g. amino acid content, secondary and tertiary structure) and/or physicochemical properties) and/or be capable of separate manufacture and/or use.

10. The Group XV, XVII and XIX inventions are drawn to independent and/or patentably distinct cyclic peptides and peptidomimetic peptides since each would be expected (and do) to possess distinctly different structure (e.g. amino acid content, secondary and tertiary structure) and/or physicochemical properties) and/or be capable of separate manufacture and/or use (e.g. purification, diagnostic or inhibition).

11. The Group XXI, XXIII, XXV, XXVII, inventions are drawn to independent and/or patentably distinct DNA or RNA compounds since each would be expected to possess distinctly different structure (e.g. single v. double strand; nucleotide composition and/or length, secondary and tertiary structure) and/or physicochemical properties (susceptibility to proteases etc) and/or be capable of separate manufacture and/or use (e.g. as probes for different genes and as inhibitors and diagnostic/therapeutic).

12. The Group XXIX and XXXI, inventions are drawn to independent and/or patentably distinct "small molecules)since each would be expected to possess distinctly different structure (e.g. primary, secondary and tertiary structure) and/or physicochemical properties (susceptibility to proteases etc) and/or be capable of separate manufacture and/or use (e.g. as inhibitors and diagnostic/therapeutic).

13. The antibodies (Groups I, III, V), chimeric proteins (Groups VII and IX), linear peptides (Groups XI and XIII), cyclic peptides (Groups XV and XVII), peptidomimetic compounds (Group XIX), DNA (Group XXI and XXV), RNA (Group XXIII and XXVII) and "small molecules" (Group XXIX and XXXI) are drawn to independent and/or patentably distinct compounds since each of these compounds possess distinctly different structure (e.g. primary, secondary and tertiary structure) and/or physicochemical properties and/or are capable of separate manufacture and/or use (e.g. as inhibitors and diagnostic/therapeutic). Additionally, these different groups do not share a core structure which elicits a specific common activity as to constitute a proper Markush listing. Accordingly, claims 1, 2, 10, 11, 20, 21,27 and 28 are drawn

to improper generic and Markush claims. The corresponding methods of use are independent and/or distinct due to the use of different patentably distinct agents (e.g.. DNA, peptides etc.) and with different objectives (e.g. inhibition and promotion of complex formation).

14. Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art as shown by their different classification;

b. the search required for the different groups is different; and/or

c. the compounds (and methods of use thereof) have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

15. The claims of Groups I-XXXII are generic to a plurality of disclosed patentably distinct species comprising peptides, proteins, antibodies, nucleotides, "small molecules" as discussed above which encompass a plethora of different compound species that requires a burdensome classification, sequence and/or biobliographic manual and computer search. Accordingly, *regardless of which group is elected,* Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g. a single compound), even though this requirement is traversed. Applicant should include a chemical structure of the elected compound if not already contained in the specification.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

~~16. A telephone call was made to on to request an oral election to the above restriction requirement, but did not result in an election being made.~~

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (703)308-0254.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa

BENNETT CELSA
PATENT EXAMINER

January 20, 1999